

OCT 27 2000

K001972

SECTION 18: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

18.1 SUBMITTER INFORMATION

- a. Company Name: IC-USA, Inc.
- b. Company Address: 2400 Boston Street
Baltimore, MD 21224
- c. Company Phone: (410) 276-1960
Company Facsimile: (410) 276-1970
- d. Contact Person: Dr. Michael Breslow
Executive Vice President
Research and Development
- e. Date Summary Prepared: June 23, 2000

18.2 DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: ARGUS System
- b. Classification Name: Network and Communication System,
Physiological Monitors
21 CFR 870.2910 74 MSX

18.3 IDENTIFICATION OF PREDICATE DEVICES

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Hewlett-Pacakard	CareVue 9000	K992636	08/31/1999
HP Agilent	Device Link	K993587	01/20/2000
VitalCom Inc.	Network Monitoring System	K962473	11/06/1997

18.4 DEVICE DESCRIPTION

The ARGUS System is the technology platform for IC-USA's Continuous Expert Care Network (CXCN). This integrated system was designed to support the delivery of clinical care to individual patient's in Intensive Care Units and to provide care givers with the ability to participate in patient management even when not physically present in the hospital. The concept of CXCN is the integration of patient care across a regional network of ICU's with a group of Intensivist/physicians working together. The Intensivist/physician team monitors the patients in the ICU network from a centralized, remote Telemedicine Center, when no on-site physician is present.

18.5 SUBSTANTIAL EQUIVALENCE

The ARGUS System is substantially equivalent to the Hewlett-Packard (Agilent) Clinical Information System (CareVue/Device Link) and the VitalCom Networked Monitoring System.

The fundamental technical characteristics of the ARGUS System are similar to those of the predicate devices. The functionality and the indications for use for the ARGUS are similar to the predicates. The ARGUS System and the predicate devices accept data patient from digital bedside monitors, contain patient databases and clinical information. The ARGUS System and the predicate devices can transfer data via LAN and WAN network technology.

18.6 INDICATIONS FOR USE

The IC-USA ARGUS System is intended for use in data collection, storage and clinical information management with independent bedside devices, and ancillary systems that are connected either directly or through networks.

The IC-USA ARGUS System is intended to provide patient information and surveillance of monitored patients at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated telephone lines.

18.7 TECHNOLOGICAL CHARACTERISTICS

The ARGUS System consists of an interactive patient care videoconferencing system, vital signs capture component, film scanner, patient management database and care management software. The care management software includes PC workstations with software to access the database, the videoconferencing and remote patient care data acquisition device and the Tool Suite software that allows the physician to write patient and medical orders for patient treatment. A Decision Support System software program is also available that can provide diagnostic and therapeutic information to the physician. Comparison of the technological characteristics to those of the predicate devices has been provided in this submission.

18.8 PERFORMANCE DATA

Performance testing was conducted on the ARGUS System. System and component testing was completed based on product specifications and hazard effects determined from the risk analysis. The ARGUS System performed as intended.

18.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2000

IC-USA, Inc.
c/o Ms. Carol White
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K001972
IC-USA's ARGUS System
Regulatory Class: II (two)
Product Code: 74 MSX
Dated: September 28, 2000
Received: September 29, 2000

Dear Ms. White:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

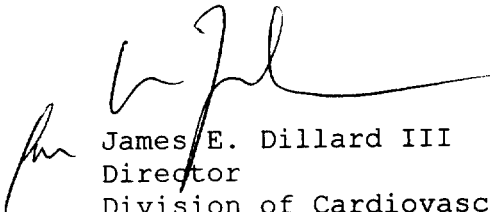
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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

INDICATION FOR USE

510(k) Number: K001972

Device Name: IC-USA ARGUS System

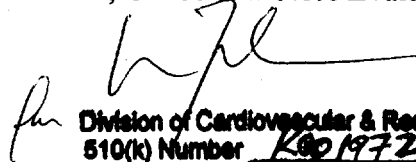
Indications for Use: The IC-USA ARGUS System is intended for use in data collection, storage and clinical information management with independent bedside devices, and ancillary systems that are connected either directly or through networks.

The IC-USA ARGUS System is intended to provide patient information and surveillance of monitored patients at the point of care location and at a remote ~~supplementary care location~~ through wide area networking technology and dedicated telephone lines.

The IC-USA ARGUS System is solely intended for use in a hospital environment. It is not intended to be used in a home environment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K001972

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

CONFIDENTIAL